UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

RACHEL PARKER, individually, and on behalf of all others similarly situated, Plaintiff, v. BAYER CORPORATION, GSK CONSUMER HEALTHCARE, INC., RITE AID CORPORATION, and WALGREEN CO., Defendants	Case No. _____ **CLASS ACTION COMPLAINT** **JURY DEMAND**

Plaintiff Rachel Parker ("Plaintiff"), by her undersigned counsel, on behalf of herself and all persons similarly situated, brings this Complaint against Defendants Bayer Corporation ("Bayer"), GSK Consumer Healthcare, Inc. ("GSK"), Rite Aid Corporation ("Rite Aid"), and Walgreen Co. ("Walgreens") (collectively, "Defendants").

NATURE OF THE ACTION

1. This case arises from the putative class members' purchase of ineffective and worthless (or, certainly worth less) over-the-counter oral or liquid (not nasal) drugs that were designed, manufactured, marketed, distributed, packaged, and/or ultimately sold by Defendants in the United States that contained phenylephrine ("PE"). Such products for Reckitt include but are not limited to: Alka-Seltzer Plus Severe Cold+Flu (Bayer), Theraflu Severe Cold & Cough (GSK), Multi-Symptom Cold & Flu Relief (Rite Aid), Sinus Pressure & Congestion Relief PE (Rite Aid), and Sinus Pressure & Pain (Walgreens).

2. All of Defendants' PE-containing products are referred to as "PE Drugs" herein.

3. Defendants' PE Drugs are marketed by them as effective for treating indications identified, most often nasal congestion.

4. On September 12, 2023, an FDA advisory panel unanimously voted 16-0 that PE is *not* effective for treating nasal congestion.[1] As stated by the panel, PE is "not effective as a nasal decongestant." Thus, it recommends avoiding unnecessary costs or delays in care by "taking a drug that has no benefit."[2]

5. At all relevant times, Defendants represented that their PE Drugs were properly branded and effective for treating the indications identified, including *inter alia* treating nasal congestion.

6. These represents were false and deceptive, as Defendants' PE Drugs were not effective for treating all the indications identified and/or were misbranded.

7. Further, each Defendant willfully ignored scientific and industry knowledge concerning the lack of effectiveness of PE Drugs for treating the indications identified, and performed inadequate testing and quality oversight of their respective PE Drugs to ascertain properly the true efficacy of their PE Drugs for treating the indications identified (principally, nasal decongestion).

8. Thus, Defendants' PE drugs are non-merchantable, not fit for ordinary purpose, and are not effective for treating the indications identified, and were misbranded as a result.

9. At all pertinent times for this action, each Defendant represented and warranted to consumers that its PE Drugs were effective for treating the indications identified and were properly branded. Specifically, each Defendant represented and

[1] C. Jewett, A Decongestant in Cold Medicines Doesn't Work at All, an F.D.A. Panel Says, NEW YORK TIMES, https://www.nytimes.com/2023/09/12/health/cold-medicine-decongestantfda.html? (last accessed Sept. 19, 2023).
[2] *Id.*

warranted that its PE Drugs were merchantable and fit for their ordinary uses (e.g., effectively treating nasal congestion).

10. However, each Defendant willfully ignored scientific and industry knowledge concerning the lack of effectiveness of PE Drugs for treating the indications identified, and performed inadequate testing and quality oversight of their respective PE Drugs to ascertain properly the true efficacy of their PE Drugs for treating the indications identified (principally, nasal decongestion).

11. Accordingly, Plaintiff brings this action to recover for the economic and related equitable or injunctive relief for themself and all other persons similarly situated who purchased Defendants' PE Drugs to redress the unlawful and deceptive practices employed by Defendants in connection with their labeling, marketing, and sale of PE Drugs.

12. Each putative class member paid for Defendants' PE Drugs, but those products were not effective for treating the indications identified and/or were misbranded, and they were not fit for ordinary purpose and were not merchantable. As a result of each Defendant's misconduct, each putative class member was damaged. Each Defendant's conduct as alleged herein constitutes breach of express and implied warranties and breach of warranty under the Magnuson Moss Warranty Act, fraud (affirmative and omission), negligent misrepresentation or omission, negligence and negligence per se, breach of consumer protection laws, and unjust enrichment.

PARTIES

A. Plaintiff

13. Plaintiff Rachel Parker is a citizen and resident of Sicklersville, New Jersey. During the class period, Plaintiff paid money for Defendants' PE Drugs. Plaintiff purchased at least one of each Defendant's PE Drugs within the applicable limitations periods, including Alka-Seltzer Plus Severe Cold+Flu (Bayer), Theraflu Severe Cold & Cough (GSK), Multi-Symptom Cold & Flu Relief (Rite Aid), Sinus Pressure & Congestion Relief PE (Rite Aid), and Sinus Pressure & Pain (Walgreens). Each Defendant expressly

and impliedly warranted to Plaintiff (either directly or indirectly by adopting warranties that were passed along to and incorporated further downstream) that their respective PE Drugs were effective at treating the indication identified and were not misbranded. Plaintiff was exposed to the product packaging and labeling at the time of each purchase, which represented and warranted the product was effective for treating the indications identified, principally nasal congestion. But in fact, Plaintiff bought PE Drugs made by each Defendant that were not effective at treating the indications identified. Had Plaintiff known this, Plaintiff would not have paid for Defendants' PE Drugs. Likewise, had each Defendant's deceptions been made known earlier, Plaintiff would not have paid for each Defendants' PE Drugs.

B. Defendants

14. Defendant Bayer is a Delaware corporation with its principal place of business at 100 Bayer Blvd., Whippany, NJ 07981. At all times material to this case, Defendant has been engaged in the manufacturing, sale, and/or distribution of misbranded and ineffective PE Drugs in the United States.

15. Defendant GSK is a Delaware corporation with its principal place of business at 184 Liberty Corner Road, Warren, New Jersey. At all times material to this case, GSK has been engaged in the manufacturing, sale, and/or distribution of misbranded and ineffective PE Drugs in the United States.

16. Defendant Rite Aid is a Pennsylvania corporation with its principal place of business at 1200 Intrepid Ave., 2nd Floor, Philadelphia, PA 19112. At all times material to this case, Rite has been engaged in the manufacturing, sale, and/or distribution of misbranded and ineffective PE Drugs in the United States.

17. Defendant Walgreens is an Illinois corporation with its principal place of business at 108 Wilmot Road., Deerfield, Illinois 60015. At all times material to this case, Walgreens has been engaged in the manufacturing, sale, and/or distribution of misbranded and ineffective PE Drugs in the United States.

JURISDICTION AND VENUE

18. This Court has original jurisdiction under the Class Action Fairness Act, 28 U.S.C. § 1332(d), because (a) at least one member of the proposed class is a citizen of a state different from that of each Defendant, (b) the amount in controversy exceeds $5,000,000, exclusive of interest and costs, (c) the proposed class consists of more than 100 class members, and (d) none of the exceptions under the subsection apply to this action.

19. This Court has personal jurisdiction over Defendants because each Defendant has sufficient minimum contacts in this state, and because each Defendant has otherwise intentionally availed itself of the markets within this state through their business activities, such that the exercise of jurisdiction by this Court is proper and necessary.

20. Venue is proper in this District because each Defendant regularly transacts its affairs in this District and at least one Defendant resides here.

21. Each Defendant is subject to the personal jurisdiction of this Court because the Defendants conduct business within this state, maintain and carry out continuous and systematic contacts within this state and this judicial District, regularly transact business within this state and this judicial District, and regularly avail themselves of the benefits of their presence in this state and this judicial District.

FACTUAL ALLEGATIONS

A. History of PE Drugs

22. Phenylephrine ("PE") is a specific alpha-1 adrenergic receptor agonist that works by temporarily constricting blood vessels. By contrast, pseudoephedrine ("PSE") is a relatively less selective agonist that acts on both alpha and beta-adrenergic receptors. The literature reports that PSE is more lipophilic than PE and thus is more accessible to the central nervous system by crossing the blood-brain barrier (Gheorghiev et al. 2018). The vasoconstriction effect of PSE is likely contributed to by an indirect action via release of norepinephrine in synaptic nerve terminals (Gorodetsky 2014).

23. The final monograph ("FM") for over-the-counter nasal decongestant drug products, issued in 1994, classified the PEH as a GRASE nasal decongestant when

administered orally (immediate-release [IR] formulations) or intranasally (M012.80, previously 21 CFR 341.80). The PEB, an IR effervescent tablet for oral administration, was added to the monograph in 2006, based on pharmacokinetic (PK) data demonstrating that it has similar bioavailability to PEH.

24. The liquid and oral (not nasal) PE drugs at issue in this case fall within two categories: (i) phenylephrine hydrochloride; and (ii) phenylephrine bitartrate.

25. The Federal Register, dated August 23, 1994 on page 433861 under section III, first allowed Phenylephrine hydrochloride to be sold: "Based on the available evidence, the agency is issuing a final monograph establishing conditions under which OTC nasal decongestant drug products are generally recognized as safe and effective and not misbranded. Specifically, the following ingredients are included in the final monograph as OTC oral nasal decongestants: Phenylephrine hydrochloride, pseudoephedrine hydrochloride, and pseudoephedrine sulfate."[3]

26. Subsequently, Phenylephrine bitartrate was included in the Federal Register on August 1, 2006 on page 833582: "The Food and Drug Administration (FDA) is issuing a final rule to amend the final monograph (FM) for over-the-counter (OTC) nasal decongestant drug products (drug products used to relieve nasal congestion due to a cold, hay fever, or other upper respiratory allergies) to add phenylephrine bitartrate (PEB), both individually and in combination drug products in an effervescent dosage form, as generally recognized as safe and effective (GRASE)."[4]

27. As a result of the market withdrawal and restrictions on the sale of other α-adrenergic agonists in the early and mid-2000s, Pfizer, Inc, introduced a replacement product (Sudafed-PE) that contained PE. Other manufacturers, including Defendants in this case, similarly followed suit by releasing products containing PE.

---

[3] Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Final Monograph for OTC Nasal Decongestant Drug Products, 59 Fed. Reg. 43386-01 (Aug. 23, 1994).

[4] Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Amendment of Monograph for OTC Nasal Decongestant Drug Products, 71 Fed. Reg. 43358-01 (Aug. 1, 2006).

B. Questions Surrounding the Efficacy of PE Drugs

28. Phenylephrine is an over-the-counter (OTC) ingredient marketed in both single ingredient and combination products. It has been available in the United States more than 75 years and globally (e.g., Canada, Australia, UK).

29. PE has largely been approved for the temporary relief of nasal congestion due to the common cold, hay fever, or other respiratory allergies, or allergic rhinitis under the cough, cold, allergy, bronchodilator, and anti-asthmatic drug products monograph ("final monograph" or "CCABADP").

30. On May 1, 2006, two professors at the University of Florida published a letter questioning the effectiveness of PE for nasal congestion based upon the results of multiple double blind, placebo-controlled studies, that show PE was no more effective than placebo in reducing nasal airway resistance.[5] Moreover, the letter notes that the studies relied on by the FDA to approve PE were unpublished, manufacturer-sponsored studies conducted by commercial testing laboratories.

31. On February 1, 2007, those professors filed a Citizens Petition with the FDA concerning PE Drugs.[6]

32. Specifically, the Petition requested the dosage of oral phenylephrine (PE) be re-evaluated and that approval for use in children under twelve years old be withdrawn.[7] The Petition further stated that there was no data on the safety of PE in children under twelve years old.[8]

33. As a result of the 2007 Citizens Petition, the FDA's Nonprescription Drugs Advisory Committee met on December 14, 2007 and concluded that the products could continue to be sold, but 9 of 12 of the committee members voted that new studies on

---

[5] L. Hendeles and R. Hatton, *Oral phenylephrine: An ineffective replacement for pseudoephedrine?*, 118 J. ALLERGY AND CLINICAL IMMUNOLOGY 279 (2006), https://www.jacionline.org/article/S0091-6749(06)00633-6/fulltext.

[6] L. Hendeles, et al., Citizens Petition to U.S. Food and Drug Admin. (Feb. 1, 2007), https://downloads.regulations.gov/FDA-2007-P-0108-0005/attachment_1.pdf.

[7] *Id.* at 1-2.

[8] *Id.* at 2-3.

response to higher doses were required.[9] Further, a member of the Division of Nonprescription Drug Products expressed a preference for subjective symptom scores over objective measurement of nasal airway resistance to support the use of PE for temporary relief of nasal congestion.[10]

34. Schering-Plough Pharmaceuticals responded to the recommendations of the Committee and the Division by conducting a multicenter, phase 2, parallel trial among 539 adults with seasonal allergic rhinitis. The results of the study revealed no significant differences between placebo and active treatment groups.[11]

35. Another manufacturer, McNeil Consumer Healthcare, conducted a pharmacokinetic, safety and cardiovascular tolerability study of PE. Similarly, this study revealed no difference in safety endpoints between placebo and 10, 20 and 30 mg of PE even though systemic exposure increased disproportionately with dose. According to the petitioners, "This is noteworthy since both the relief of congestion and systemic endpoints such as change in blood pressure and pulse are mediated by alpha adrenergic stimulation. The absence of a significant effect on the latter at the higher doses suggest that the concentrations reached are not sufficient to stimulate alpha adrenergic receptors."[12]

36. On November 4, 2015, the authors of the 2007 Citizen Petition filed an additional Citizens Petition asking the FDA "to remove oral phenylephrine from the Final Monograph for OTC nasal decongestant products." Specifically, the petition asked the FDA to remove Phenylephrine and to remove phenylephrine bitartrate (PEB), "both individually and in combination drug products in an effervescent dosage form[.]"[13]

---

[9] U.S. Food and Drug Admin., Summary Minutes of the NDAC meeting (Dec. 14, 2007), avail. at https://wayback.archive-it.org/7993/20170403222236/https://www.fda.gov/ohrms/dockets/ac/07/minutes/2007-4335m1-Final.pdf (last accessed Sep. 19, 2023).

[10] L. Hendeles and R. Hatton, Citizens Petition to U.S. Food and Drug Admin. (Nov. 4, 2015), avail. at https://truthinadvertising.org/wp-content/uploads/2023/02/Hatton-Hendeles-2015-Citizens-Petition-re-oral-phenylephrine.pdf, at 2.

[11] *Id.*

[12] *Id.* at 3.

[13] *Id.* at 1.

37. According to the 2015 Citizens Petition, "Two additional studies published in 2009 provide further evidence of the absence of a decongestant effect from the FDA-approved nonprescription dose of 10 mg. Horak et al conducted a 3-way crossover, placebo-controlled study of the nasal decongestant effect of single doses of PE 12 mg, pseudoephedrine 60 mg or placebo among 39 grass-sensitive adults exposed to grass pollen in the Vienna Challenge Chamber. PE was not significantly different from placebo in the mean change in subjective nasal congestion scores whereas pseudoephedrine, a positive control in the study, decreased congestion significantly greater than placebo and PE."[14]

38. The 2015 Citizens Petition was further supported by the American Academy of Allergy, Asthma & Immunology.[15]

39. On information and belief, at this time, each Defendant did not do additional testing and quality oversight of their respective PE Drugs to ascertain the true effectiveness for treating nasal congestion, or deliberately suppressed or avoid doing so. Had they done so and/or disclosed the results, the data would lead to the same inexorable conclusion reached on September 12, 2023 by an FDA Advisory Panel: PE is not effective for treating nasal congestion at all.

C. The FDA Advisory Panel's Unanimous Vote

40. On September 12, 2023, the FDA Advisory Panel on the Division of Nonprescription Drugs recommended that PE Drugs not be sold due to lack of efficacy.[16]

41. In the FDA's Briefing Document regarding the hearing that took place on September 11-12, 2023, the FDA notes that it has been reviewing the clinical studies on the efficacy of PE since the 2007 Citizens Petition.[17]

42. The Advisory Panel concluded,

---

[14] *Id.* at 4.
[15] Am. Academy of Allergy, Asthma & Immunology, Statement of Support of Citizens Petition (May 4, 2022), avail. at https://college.acaai.org/wp-content/uploads/2022/05/oral-phenylephrinefinal-statement-in-support-of-citizens-petition-05-4-22.pdf (last accessed Sep. 19, 2023).
[16] U.S. Food and Drug Admin., Efficacy of Oral Phenylephrine as a Nasal Decongestant (Sep. 12, 2023), https://www.fda.gov/media/171915/download.
[17] *Id.*

> In accordance with the effectiveness standard for determining that a category of over-the-counter (OTC) drugs is generally recognized as safe and effective that is set forth in 21 CFR § 330.10(a)(4)(ii), which defines effectiveness as: "a reasonable expectation that, in a significant proportion of the target population, the pharmacological effect of the drug, when used under adequate directions for use and warnings against unsafe use, will provide clinically significant relief of the type claimed", we have now come to the initial conclusion that orally administered PE is not effective as a nasal decongestant at the monographed dosage (10 mg of PE hydrochloride every 4 hours) as well as at doses up to 40 mg (dosed every 4 hours).[18]

43. The Advisory Panel met for two days on September 11-12, 2023. During this meeting, FDA scientists presented the results of five studies conducted over the past two decades on the effectiveness of oral phenylephrine. All the studies concluded that the decongestant was no more effective than a placebo. The Advisory Panel further reevaluated the initial findings which supported PE Drugs' use and found that the results were inconsistent, did not meet modern study design standards and further that these studies may have data integrity issues:[19]

> "In conclusion, we do believe that the original studies were methodologically unsound and do not match today's standard. By contrast, we believe the new data are credible and do not provide evidence that oral phenylephrine is effective as a nasal decongestant," said Dr. Peter Starke, an FDA official who led the review of phenylephrine.[20]

44. At the conclusion of the meetings, members voted unanimously (16-0) that PE drugs were ineffective, paving the way for the drugs to be removed from the market.

45. Following this vote by the Advisory Panel, the FDA will now need to decide whether PE Drugs can still be sold and whether drugs should lose their designation as Generally Recognized as Safe and Effective (GRASE).

D. Misbranded Drugs Are Illegal to Sell

---

[18] *Id.*

[19] B. Lovelace, FDA panel says common over-the-counter decongestant doesn't work, NBC NEWS (Sep. 12, 2023), https://www.nbcnews.com/health/health-news/fda-panel-says-commoncounter-decongestant-phneylephrine-doesnt-work-rcna104424 (last accessed Sep. 19. 2023).

[20] *Id.*

46. Any drug not manufactured in accordance with cGMPs is deemed "adulterated" or "misbranded" and may not be distributed or sold in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B). States have enacted laws adopting or mirroring these federal standards.

47. A drug is misbranded:

a. "If its labeling is false or misleading in any particular"[21];

b. "If any word, statement, or other information required … to appear on the label or labeling is not prominently placed thereon…in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use"[22];

c. If the labeling does not contain, among other things, "the proportion of each active ingredient"[23];

d. "Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings … against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users"[24];

e. "If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein"[25]

f. "if it is an imitation of another drug"[26];

g. "if it is offered for sale under the name of another drug"[27];

[21] 21 U.S.C. § 352(a)(1).
[22] 21 U.S.C. § 352(c).
[23] 21 U.S.C. § 352(e)(1)(A)(ii).
[24] 21 U.S.C. § 352(f).
[25] 21 U.S.C. § 352(g).
[26] 21 U.S.C. § 352(i)(2).
[27] 21 U.S.C. § 352(i)(3).

h. "If it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof"[28];

i. If the drug is advertised incorrectly in any manner[29]; and/or

j. If the drug's "packaging or labeling is in violation of an applicable regulation."[30]

48. The manufacture and sale of any misbranded drug is prohibited under federal law.[31]

49. The introduction into commerce of any misbranded drug is also prohibited.[32]

50. Similarly, the receipt in interstate commerce of any misbranded or misbranded drug is also unlawful.[33]

51. As articulated in this Complaint, Defendant's sale of PE Drugs that were not effective for treating the indications identified were misbranded in violation of the above-cited reasons.

52. Plaintiff's reference federal law in this Complaint not in any attempt to enforce it, but to demonstrate that their state-law tort claims do not impose any additional obligations on any Defendant, beyond what is already required of them under federal law.

i. Defendant Made False Statements in the Labeling

53. A manufacturer must give adequate directions for the use of a pharmaceutical drug so that a "layman can use a drug safely and for the purposes for which it is intended,"[34] and conform to requirements governing the appearance of the label.[35]

[28] 21 U.S.C. § 352(j).
[29] 21 U.S.C. § 352(n).
[30] 21 U.S.C. § 352(p).
[31] 21 U.S.C. § 331(g).
[32] 21 U.S.C. § 331(a).
[33] 21 U.S.C. § 331(c).
[34] 21 C.F.R. § 201.5.
[35] 21 C.F.R. § 801.15.

54. "Labeling" encompasses all written, printed or graphic material accompanying the drug or device,[36] and therefore broadly includes nearly every form of promotional activity, including not only "package inserts" but also advertising.

55. "Most, if not all, labeling is advertising. The term 'labeling' is defined in the FDCA as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising."[37]

56. Because the labels on Defendants' PE drugs indicate that PE can be used to treat nasal congestion, the subject drugs were misbranded.

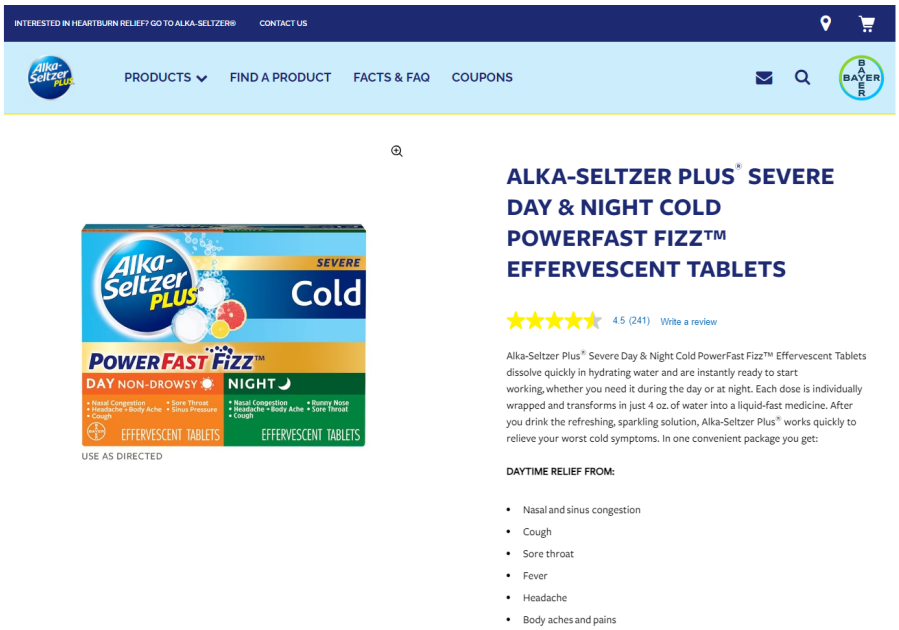
57. It is unlawful to introduce a misbranded drug into interstate commerce.[38] Thus, the PE Drugs ingested by Plaintiff were unlawfully distributed and sold.

ii. Each Defendant's Warranties and Fraudulent and Deceptive Statements to Consumers Regarding Their VCDs

58. Each Defendant made and breached express and implied warranties and made affirmative misrepresentations and omissions to consumers about their PE Drugs.

59. Defendant Bayer postured its PE Drugs as effective for treating nasal congestion. For example:

[36] *Id.* 65 Fed. Reg. 14286 (March 16, 2000).
[37] *U.S. v. Research Labs.,* 126 F.2d 42, 45 (9th Cir. 1942).
[38] 21 U.S.C. § 331(a).



60. Bayer's PE Drugs contained PE as well:

Alka-Seltzer Plus Severe Cold PowerFast Fizz Day & Night (Effervescent Tablets) Co-Packaged Product

Do not take these products at the same time.

Alka-Seltzer Plus® Severe Cold PowerFast Fizz Day Effervescent Tablets

Drug Facts

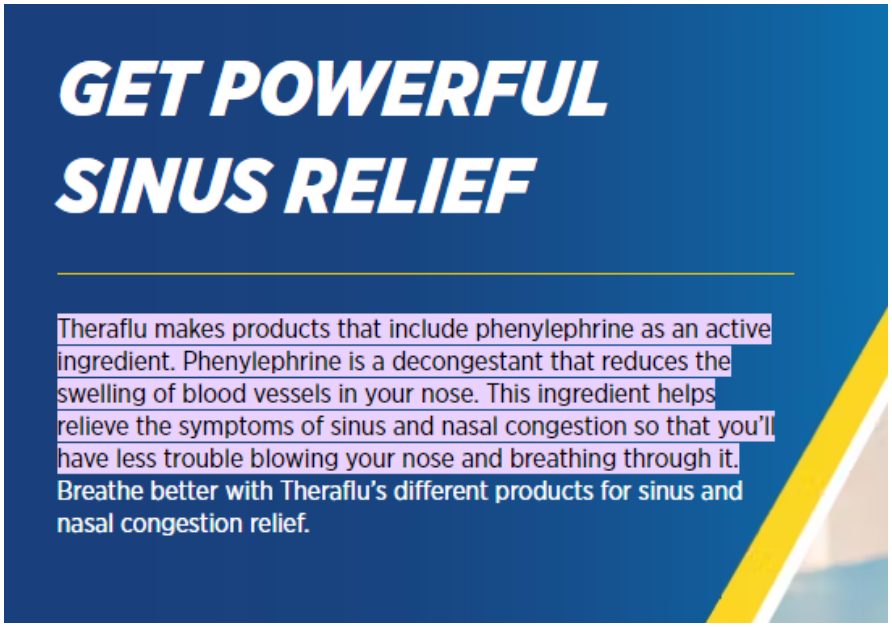
Active ingredients (in each tablet)	***Purposes***
Aspirin 325 mg (NSAID)*	Pain reliever/fever reducer
Dextromethorphan hydrobromide 10 mg	Cough suppressant
Phenylephrine bitartrate 7.8 mg	Nasal decongestant

*nonsteroidal anti-inflammatory drug

Uses

- temporarily relieves these symptoms due to a cold with cough:
  - minor aches and pains
  - headache
  - cough
  - sinus congestion and pressure
  - nasal congestion
  - sore throat
- temporarily reduces fever

61. Similarly, Defendant GSK paraded its own PE Drugs' effectiveness at treating nasal congestion. For instance, GSK promised that its PE Products would provide relief for nasal congestion:



62. Rite Aid's website, product packaging, and advertisements touted the drugs' effectiveness at treating nasal congestion:

PRODUCT DETAILS

Item No. 0304174

Phenylephrine hydrochloride. Pseudoephedrine free. Relieves: nasal congestion; sinus congestion without drowsiness. 1 pill per dose. Compare to the active ingredient in Sudafed PE tablets (This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Sudafed PE).

MORE INFORMATION

Product Name	Rite Aid Pharmacy Nasal Decongestant PE Tablets, 10mg - 18 ct
Sub Brand	Rite Aid Pharmacy
Package Count	18
Container Type	other
Form	Tablet
Best For	Congestion
Prop 65	No

63. Walgreens made similar representations about its PE Drugs' effectiveness for nasal congestion, claiming its products will relieve congestion:

64. Defendants' representations on their website, product packaging, product label, and other advertisements and promotions, were false and misleading. Contrary to Defendants' statements, and undisclosed by Defendants, PE was not effective at all for treating nasal congestion. Defendants knew, or should have known, this.

2. ***Fraudulent Concealment and Tolling***

60. Plaintiff's and Class Members' causes of action accrued on the date the FDA announced that PE was not effective at treating the indications identified in Defendants' PE Drug labeling and packaging, that is, September 12, 2023. This is the first date when Plaintiffs and Class Members could have reasonably discovered Defendants' unlawful methods, acts, and/or practices as described herein.

61. Each Defendant affirmatively concealed from Plaintiff and other Class

Members its unlawful conduct. Each Defendant affirmatively strove to avoid disclosing their knowledge of the ineffectiveness of their respective PE Drugs for treating the indications identified, and/or that such products were misbranded.

62. For instance, no Defendant revealed to the public that their PE Drugs were *not* effective at treating the indications identified, or that in fact PE was not effective at all to treat same (principally, nasal decongestion), despite reasons to believe the contrary due to their superior knowledge and position and the manufacturer or seller of their respective PE Drugs.

63. To the contrary, each Defendant continued to represent and warrant that its respective PE Drugs were effective for treating the indications identified, principally nasal decongestion.

64. Because of this, Plaintiff and other Class Members did not discover, nor could they have discovered through reasonable and ordinary diligence, each Defendant's deceptive, fraudulent, and unlawful conduct alleged herein.

65. As a result of each Defendant's affirmative and other acts of concealment, any applicable statute of limitations affecting the rights of Plaintiff and other Class Members has been tolled. Plaintiff and/or other Class Members exercised reasonable diligence by among other things promptly investigating and bringing the allegations contained herein. Despite these or other efforts, Plaintiff was unable to discover, and could not have discovered, the unlawful conduct alleged herein at the time it occurred or at an earlier time so as to enable this complaint to be filed sooner.

CLASS ACTION ALLEGATIONS

66. Plaintiff seeks to represent a Nationwide Class pursuant to Fed. R. Civ. P. 23(a), 23(b)(2) and 23(b)(3) as defined below:

> **National Class:** All individuals and entities in the United States and its territories and possessions who paid any amount of money for any Defendant's PE Drugs (intended for personal or household use).
>
> **New Jersey Subclass:** All individuals and entities in New Jersey who paid any amount of money for any Defendant's PE Drugs (intended for personal or household use).

67. Plaintiff alleges additional sub-classes for all Class Members in each State, territory, or possession – or combination(s) of States, territories, or possessions to the extent class members from these jurisdictions can be grouped together for purposes of class treatment – who, paid any amount of money for PE Drugs (intended for personal or household use) that was manufactured, distributed, or sold by any Defendant (collectively, the "Subclasses").

68. Collectively, the foregoing Nationwide Class and the Subclasses are referred to as the "Class."

69. Excluded from the Class are: (a) any judge or magistrate presiding over this action, and members of their families; (b) Defendants and affiliated entities, and their employees, officers, directors, and agents; (c) Defendants' legal representatives, assigns and successors; and (d) all persons who properly execute and file a timely request for exclusion from any Court-approved class.

70. Plaintiff reserves the right to narrow or expand the foregoing class definition, or to create or modify subclasses as the Court deems necessary.

71. Plaintiff meets the prerequisites of Rule 23(a) to bring this action on behalf of the Class.

72. **Numerosity**: Membership in the Class is so numerous that separate joinder of each member is impracticable. The precise number of Class Members is unknown at this time but can be readily determined from Defendants' records. Plaintiffs reasonably estimate that there are at least thousands of persons in the Class.

73. **Existence and predominance of common questions of law and fact:** Common questions of law and fact exist as to all Class and Subclass Members and predominate over any questions affecting on individual Class and Subclass members. These common legal and factual questions include, but are not limited to, the following:

a. Whether each Defendant made express or implied warranties that their respective PE Drugs were effective for treating the indications identified (principally, nasal decongestion);

b. Whether each Defendant's PE Drugs were not effective for treating the indications identified (principally, nasal decongestion);

c. Whether each Defendant knew or should have known the truth about the effectiveness or lack thereof for their respective PE Drugs;

d. Whether Plaintiff and other Class Members have been injured as a result of each Defendant's unlawful conduct, and the amount of their damages;

e. Whether a common damages model can calculate damages on a class-wide basis;

f. When Plaintiff's and Class Members' causes of action accrued; and

g. Whether each Defendant fraudulently concealed Plaintiff's and Class Members' causes of action.

74. **Typicality**: Plaintiff's claims are typical of Class Members' claims. Plaintiff and Class Members all suffered the same type of economic harm. Plaintiff has substantially the same interest in this matter as all other Class Members, and their claims arise out of the same set of facts and conduct as the claims of all other Class Members.

75. **Adequacy of Representation**: Plaintiff is committed to pursuing this action and have retained competent counsel experienced in pharmaceutical litigation, consumer fraud litigation, class actions, and federal court litigation. Accordingly, Plaintiff and their counsel will fairly and adequately protect the interests of Class Members. Plaintiff's claims are coincident with, and not antagonistic to, those of the other Class Members they seek to represent. Plaintiff has no disabling conflicts with Class Members and will fairly and adequately represent the interests of Class Members.

76. The elements of Rule 23(b)(2) are met. Defendant has acted on grounds that apply generally to Class Members so that preliminary and/or final injunctive relief and corresponding declaratory relief is appropriate respecting the Class as a whole.

77. **Superiority**: A class action is superior to all other available means for the fair and efficient adjudication of this controversy. Although many other Class Members have claims against each Defendant, the likelihood that individual Class Members will prosecute separate actions is remote due to the time and expense necessary to conduct such litigation.

Serial adjudication in numerous venues would not be efficient, timely or proper. Judicial resources would be unnecessarily depleted by resolution of individual claims. Joinder on an individual basis of thousands of claimants in one suit would be impractical or impossible. In addition, individualized rulings and judgments could result in inconsistent relief for similarly situated Plaintiff. Plaintiff's counsel, highly experienced in pharmaceutical litigation, consumer fraud litigation, class actions, and federal court litigation, foresee little difficulty in the management of this case as a class action.

CAUSES OF ACTION

FIRST COUNT

BREACH OF EXPRESS WARRANTIES

78. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth herein.

79. Plaintiff, and each member of the Class, formed a contract with each Defendant at the time Plaintiff and the other Class Members purchased the PE Drugs. The terms of the contract include the promises and affirmations of fact made by Defendant on the PE Drugs' packaging and through marketing and advertising, including that the product would be effective for the indications provided. This labeling, marketing, and advertising constitute express warranties and became part of the basis of the bargain, and are part of the standardized contract between Plaintiff and the members of the Class and Defendants.

80. Each Defendant expressly warranted that its PE Drugs were fit for ordinary use and effective for the indications listed and were merchantable and not misbranded.

81. Each Defendant sold PE Drugs that they expressly warranted to be effective

at treating the indications identified and were not misbranded.

82. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code: Ala. Code § 7-2-313; Alaska Stat. § 45.02.313; Ariz. Rev. Stat. Ann. § 47-2313; Ark. Code. Ann. § 4-2-313; Cal. Com. Code § 2313; Colo. Rev. Stat. § 4-2-313; Conn. Gen. Stat. Ann. § 42a-2-313; 6 Del. Code. § 2-313; D.C. Code. § 28:2-313; Fla. Stat. Ann. § 672.313; Ga. Code. Ann. § 11-2-313; Haw. Rev. Stat. § 490:2- 313; Idaho Code § 28-2-313; 810 Ill. Comp. Stat. Ann. 5/2-313; Ind. Code Ann. § 26-1-2-313; Kan. Stat. Ann. § 84-2-313; Ky. Rev. Stat. Ann. § 355.2-313; La. Civ. Code Ann. Art. §§ 1943, 2520; 11 Me. Rev. Stat. Ann. § 2-313; Md. Code. Ann. § 2-313; Mass. Gen. Law Ch. 106 § 2-313; Mich. Comp. Laws Ann. § 440.2313; Minn. Stat. Ann. § 336.2-313; Miss. Code Ann. § 75-2-313; Mo. Rev. Stat. § 400.2-313; Mont. Code Ann. § 30-2-313; Nev. Rev. Stat. U.C.C. § 104.2313; N.H. Rev. Ann. § 382-A:2-313; N.J. Stat. Ann. § 12A:2-313; N.M. Stat. Ann. § 55-2-313; N.Y. U.C.C. Law § 2-313; N.C. Gen. Stat. Ann. § 25-2-313; N.D. Stat. § 41-02-313; Ohio Rev. Code Ann. § 1302.26; Okla. Stat. tit. 12A § 2-313; Or. Rev. Stat. § 72.3130; 13 Pa. C.S. § 2313; P.R. Laws. Ann. Tit. 31, § 3841, et seq.; R.I. Gen. Laws § 6A-2-313; S.C. Code Ann. § 36-2-313; S.D. Stat. § 57A-2-313; Tenn. Code Ann. § 47-2-313; Tex. Bus. & Com. Code Ann. § 2-313; Utah Code Ann. § 70A-2-313; Va. Code § 8.2- 313; Vt. Stat. Ann. 9A § 2-313; W. Va. Code § 46-2-313; Wash. Rev. Code § 62A 2-313; Wis. Stat. Ann. § 402.313; and Wyo. Stat. § 34.1-2-313.

83. Each Defendant knew or should have known that its PE Drugs were being

manufactured and sold for the intended purpose of human consumption for treating the indications identified (or is strictly liable in the event of lack of actual or constructive knowledge), and impliedly warranted that their PE Drugs were of merchantable quality and fit for that purpose.

84. Each Defendant breached its express warranty because each Defendant's PE Drugs were not of merchantable quality, nor fit for the product's ordinary purpose, and did not conform to the standards generally applicable to such goods.

85. Each Defendant's express warranties were reflected in each PE Drug's product labeling (e.g., label, instructions, packaging) and promotion and marketing material, all of which uniformly identified PE as an active ingredient for effective treatment of the indications identified, principally nasal decongestion. Each Defendant's product labeling and other materials had to be truthful, accurate, and non-deceptive. But this was not the case, insofar as each Defendant's product labeling and other materials did not disclose that PE is not effective for the indications identified, principally nasal congestion.

86. Each Defendant's PE Drugs did not fulfill their intended purpose. Plaintiff and other Class Members bargained for an adequately made, adequately labeled product, that performed as warranted. But each Defendant's PE Drugs were not adequately made, were not adequately labeled, and did not perform as warranted.

87. Plaintiff and other Class Members purchased the PE Drugs in reliance upon Defendant's skill and judgment and the express warranties made.

88. Plaintiff and other Class Members were reasonably expected purchasers who

would use, consumer or be affected by (or whose insureds would use, consumer or be affected by) the misbranded, not effective PE Drugs marketed by each Defendant.

89. The PE Drugs were not altered by Plaintiff or Class members.

90. As a direct and proximate result of each Defendant's breach of implied warranty, Plaintiff and other Class Members have been injured and suffered damages, in that Defendant's PE Drugs they purchased was so inherently flawed, unfit, or unmerchantable as to have significantly diminished or no intrinsic market value.

91. To the extent applicable, pre-suit notice and/or a demand letter was sent to each Defendant prior to the filing of the Complaint.

SECOND COUNT
BREACH OF IMPLIED WARRANTIES

92. Plaintiff re-alleges and incorporates the preceding paragraphs as if full set forth herein.

93. Plaintiff, and each member of the Class, formed a contract with each Defendant at the time Plaintiff and the other Class Members purchased the PE Drugs. The terms of the contract include the promises and affirmations of fact made by Defendant on the PE Drugs' packaging and through marketing and advertising, including that the product would be effective for the indications provided. This labeling, marketing, and advertising constitute express warranties and became part of the basis of the bargain, and are part of the standardized contract between Plaintiff and the members of the Class and Defendants.

94.At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose: Ala. Code § 7-2-314; Alaska Stat. § 45.02.314; Ariz. Rev. Stat. Ann. § 47-2314; Ark. Code. Ann. § 4-2-314; Cal. Com. Code § 2314; Colo. Rev. Stat. § 4-2-314; Conn. Gen. Stat. Ann. § 42a-2-314; 6 Del. Code. § 2-314; D.C. Code. § 28:2-314; Fla. Stat. Ann. § 672.314; Ga. Code. Ann. § 11-2-314; Haw. Rev. Stat. § 490:2- 314; Idaho Code § 28-2-314; 810 Ill. Comp. Stat. Ann. 5/2-314; Kan. Stat. Ann. § 84-2-314; Ky. Rev. Stat. Ann. § 355.2-314; ; La. Civ. Code Ann. Art. § 2520; 11 Me. Rev. Stat. Ann. § 2-314; Md. Code. Ann. § 2-314; Mass. Gen. Law Ch. 106 § 2-314; Mich. Comp. Laws Ann. § 440.2314; Minn. Stat. Ann. § 336.2-314; Miss. Code Ann. § 75-2-314; Mo. Rev. Stat. § 400.2-314; Mont. Code Ann. § 30-2-314; Nev. Rev. Stat. U.C.C. § 104.2314; N.H. Rev. Ann. § 382-A:2-314; N.J. Stat. Ann. § 12A:2-314; N.M. Stat. Ann. § 55-2-314; N.Y. U.C.C. Law § 2-314; N.C. Gen. Stat. Ann. § 25-2-314; N.D. Stat. § 41-02-314; Ohio Rev. Code Ann. § 1302.27; Okla. Stat. tit. 12A § 2-314; Or. Rev. Stat. § 72.3140; 13 Pa. C.S. § 2314; P.R. Laws. Ann. Tit. 31, § 3841, et seq.; R.I. Gen. Laws § 6A-2-314; S.C. Code Ann. § 36-2-314; S.D. Stat. § 57A-2-314; Tenn. Code Ann. § 47-2-314; Tex. Bus. & Com. Code Ann. § 2-314; Utah Code Ann. § 70A-2-314; Va. Code § 8.2-314; Vt. Stat. Ann. 9A § 2-314; W. Va. Code § 46-2-314; Wash. Rev. Code § 62A 2-314; Wis. Stat. Ann. § 402.314; and Wyo. Stat. § 34.1-2-314.

95.Each Defendant was a merchant within the meaning of the above statutes.

96.Each Defendant's PE Drugs constituted "goods" or the equivalent within the

meaning of the above statutes. Each Defendant placed their PE Drugs in sealed packaging or other closed containers and placed them on the market.

97. Each Defendant impliedly warranted that its PE Drugs were fit for ordinary use and effective for the indications listed and were merchantable and not misbranded.

98. Each Defendant sold PE Drugs that they impliedly warranted to be effective at treating the indications identified and were not misbranded.

99. Each Defendant knew or should have known that its PE Drugs were being manufactured and sold for the intended purpose of human consumption for treating the indications identified (or is strictly liable in the event of lack of actual or constructive knowledge), and impliedly warranted that their PE Drugs were of merchantable quality and fit for that purpose.

100. Each Defendant breached its implied warranty because each Defendant's PE Drugs were not of merchantable quality, nor fit for the product's ordinary purpose, and did not conform to the standards generally applicable to such goods.

101. Plaintiff and other Class Members purchased the PE Drugs in reliance upon Defendant's skill and judgment and the implied warranties of fitness for the purpose.

102. Each Defendant's PE Drugs did not fulfill their intended purpose. Plaintiff and other Class Members bargained for an adequately made, adequately labeled product, that performed as warranted. But each Defendant's PE Drugs were not adequately made, were not adequately labeled, and did not perform as warranted.

103. Each Defendant's implied warranties were reflected in each PE Drug's

product labeling (e.g., label, instructions, packaging) and promotion and marketing material, all of which uniformly identified PE as an active ingredient for effective treatment of the indications identified, principally nasal decongestion. Each Defendant's product labeling and other materials had to be truthful, accurate, and non-deceptive. But this was not the case, insofar as each Defendant's product labeling and other materials did not disclose that PE is not effective for the indications identified, principally nasal congestion.

104. Each Defendant's PE Drugs did not fulfill their intended purpose. Plaintiff and other Class Members bargained for an adequately made, adequately labeled product, that performed as warranted. But each Defendant's PE Drugs were not adequately made, were not adequately labeled, and did not perform as warranted.

105. Plaintiff and other Class Members purchased the PE Drugs in reliance upon Defendant's skill and judgment and the express warranties made.

106. Plaintiff and other Class Members were reasonably expected purchasers who would use, consumer or be affected by (or whose insureds would use, consumer or be affected by) the misbranded, not effective PE Drugs marketed by each Defendant.

107. Plaintiff and other Class Members were the intended third-party beneficiary recipients of all arrangements Defendant had with downstream resellers of Defendant's PE Drugs. Plaintiffs and other Class Members were those whose benefit any promises, affirmations, or warranties were made by Defendant concerning the PE Drugs, as they were the intended end purchasers and end users (or, in the case of entities, their insureds were the intended end users) of Defendant's PE Drugs, which Defendant knew by virtue of its

position as manufacturer and seller of the PE Drugs.

108. The PE Drugs were not altered by Plaintiff or Class members.

109. As a direct and proximate result of each Defendant's breach of implied warranty, Plaintiff and other Class Members have been injured and suffered damages, in that Defendant's PE Drugs they purchased were so inherently flawed, unfit, or unmerchantable as to have significantly diminished or no intrinsic market value.

110. To the extent applicable, pre-suit notice and/or a demand letter was sent to each Defendant prior to the filing of the Complaint.

THIRD COUNT
MAGNUSON-MOSS WARRANTY ACT, 15 U.S.C. § 2301, *ET SEQ.*

111. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth herein.

112. Each Defendant is a "warrantor" within the meaning of the Magnuson-Moss Warranty Act.

113. Plaintiff and other Class Members are "consumers" within the meaning of the Magnuson-Moss Warranty Act.

114. Each Defendant expressly or impliedly warranted their PE Drugs as alleged in the First and Second Causes of Action.

115. Under 15 U.S.C. § 2310(d)(1), Plaintiff and other Class Members were "damaged by the failure of a supplier, warrantor, or service contractor to comply with any

obligation under this chapter, or under a written warranty, implied warranty, or service contract, may bring suit for damages and other legal and equitable relief." 15 U.S.C. § 2310(d)(1). Plaintiff sues pursuant to this section to recover money damages and for legal and equitable relief on behalf of itself and the Class Members.

116. Each Defendant has not acted on the opportunity to cure its failure with respect to its warranted PE Drugs.

117. Likewise, pursuant to 15 U.S.C. § 2310(d)(2), upon prevailing in this action, Plaintiffs are entitled to receive an award of attorneys' fees and expenses and pray for the same.

FOURTH COUNT

FRAUD (AFFIRMATIVE MISRREPRESENATION AND OMISSION)

118. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth herein.

119. Each Defendant affirmatively misrepresented material facts including, inter alia, that their PE Drugs were effective at treating the indications identified and/or were not misbranded.

120. Each Defendant omitted material facts including, inter alia, that their PE Drugs were not effective at treating the indications identifies and/or were misbranded.

121. Each Defendant's actions had the effect of fraudulently inducing customers to pay in whole or in part for each Defendant's PE Drugs – products which each Defendant knew or should have known were not effective at treating the indications identified and/or were misbranded. Plaintiff and other Class Members would not have purchased

Defendants' PE Drugs had they known the truth. Indeed, Plaintiff and other Class Members could not have paid for Defendants' PE Drugs had they known the truth because Defendants' PE Drugs were illegally manufactured, illegally imported, illegally distributed, and illegally sold to Plaintiffs and Class Members based on each Defendants' fraudulent misrepresentations and omissions.

122. Each Defendant knew or should have known about the effectiveness and branding status of its PE Drugs as a result of industry and regulatory guidance dating back years.

123. Each Defendant knowingly, or at least recklessly, represented that its PE Drugs were effective in treating the indications identified and not misbranded, when that was not the case. Rather, each Defendant knew or recklessly disregarded industry and regulatory guidance that was available to each Defendant.

124. Each Defendant knew, or reasonably should have known, that their misrepresentations were materially false or misleading, or that the omission of material facts rendered such representations false or misleading.

125. Each Defendant also knew, or had reason to know, that their misrepresentations and omissions would induce Class Members to pay for some or all of the cost of Defendant's PE Drugs.

126. Each Defendant's misrepresentations and omissions were material.

127. Each Defendant's actively concealed their misrepresentations and omissions from the Class, government regulators, and the public.

128. To the extent applicable, each Defendant intended their misrepresentations and omissions to induce Plaintiffs and other Class Members to pay for each Defendant's PE Drugs.

129. But for these misrepresentations and omissions, Plaintiff and other Class Members would not have paid for each Defendant's PE Drugs.

130. To the extent applicable, Plaintiff and other Class Members were justified in relying on each Defendant's misrepresentations and omissions. The same or substantively identical misrepresentations and omissions were communicated, to each Class Member, including through product labeling and other statements by each Defendant. No reasonable consumer would have paid what they did for Defendants' PE Drugs but for Defendants' unlawful conduct. To the extent applicable, reliance may be presumed in these circumstances.

131. Plaintiff and other Class Members were damaged by reason of Defendants' misrepresentations and omissions alleged herein.

FIFTH COUNT

NEGLIGENT MISREPRESENTATION AND OMISSION

132. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth herein.

133. Each Defendant had or undertook a duty to represent the effectiveness of its PE Drugs accurately and truthfully.

134. Each Defendant failed to exercise ordinary care in making representations (or in failing to disclose facts) concerning the effectiveness of its PE Drugs.

135. Each Defendant negligently misrepresented or omitted facts regarding the effectiveness of its PE Drugs.

136. Defendant's statements were false at the time the misrepresentations were made (or at the time omissions were not made).

137. Each Defendant knew, or reasonably should have known, that its representations alleged herein were materially false or misleading, or that omission of material facts rendered such representations false or misleading. Each Defendant also knew, or had reason to know, that its misrepresentations and omissions would induce Class Members to make purchases of each Defendant's PE Drugs.

138. Each Defendant had a duty to exercise reasonable care in the manufacture, quality control, and distribution of PE Drugs. Each Defendant's failure to exercise this duty, in spite of knowing or recklessly disregarding the effectiveness of its PE Drugs, meant Defendants could not assure that their PE Drugs were of as represented effectiveness.

139. As a direct and proximate result of Defendants' acts and omissions described herein, Plaintiffs and other Class Members have suffered harm, and will continue to do so.

140. Each Defendant's misrepresentations or omissions were material and a substantial factor in Plaintiffs' and other Class Members' paying for PE Drugs.

141. Each Defendant intended its misrepresentations or omissions to induce Plaintiff and Class Members to make purchases of PE Drugs, or had reckless disregard for same.

142. But for these misrepresentations (or omissions), Plaintiff and other Class Members would not have made purchases of Defendants' PE Drugs.

143. Plaintiff and other Class Members were justified in relying on Defendants' misrepresentations or omissions. The same or substantively identical misrepresentations were communicated, and/or the same or substantively identical omissions were not communicated, to each Class Member.

144. Plaintiff and other Class Members were damaged by reason of each Defendant's misrepresentations or omissions alleged herein.

SIXTH COUNT
VIOLATION OF STATE CONSUMER PROTECTION LAWS

145. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth herein.

146. Each Defendant has violated the consumer protection statutes as follows:

a. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ala. Code § 8-19-1, *et seq.*;

b. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. § 45.50.471, *et seq.*;

c. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Arizona Rev. Stat. § 44-1522, *et seq.*;

d. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq.*;

e. Defendants have violated the California Unfair Competition Law by

engaging in unfair or deceptive acts or practices in violation of Cal. Bus. Prof. Code § 17200, *et seq.*;

f. Defendants have violated the California Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750, *et seq.*;

g. Defendants have violated the California False Advertising Law, Cal. Bus. & Prof. Code §§ 17500, *et seq.*

h. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Colo. Rev. Stat. § 6-1-105, *et seq.*;

i. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, *et seq.*;

j. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, *et seq.*;

k. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of D.C. Code § 28-3901, *et seq.*;

l. Defendant have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq.*;

m. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. State 10-1-392, *et seq.*;

n. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, *et seq.*;

o. Defendants have engaged in unfair competition or unfair or deceptive

acts or practices in violation of Idaho Code § 48-601, *et seq*.;

p. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation 815 ILCS 505/1, *et seq.*;

q. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5.1, *et seq.*;

r. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code Ann. § 714H, *et seq.*;

s. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et seq.*;

t. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.110, *et seq.*;

u. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401, et seq. and alternatively La. Rev. Stat. Ann. § 9:2800.51, et seq;

v. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 207, *et seq.*;

w. Defendant have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq.*;

x. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*;

y. Defendants have engaged in unfair competition or unfair or deceptive

acts or practices in violation of Mich. Stat. § 445.901, *et seq.*;

z. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 325F.67, *et seq.*;

aa. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Miss. Code Ann. § 75-24-1, *et seq.*;

bb. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mo. Rev. Stat. § 407.0 10, *et seq.*;

cc. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30-14-101, *et seq.*;

dd. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*;

ee. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, *et seq.*;

ff. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*;

gg. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.J. Stat. Ann. § 56:8-1, *et seq.*;

hh. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. § 57-12-1, *et seq.*;

ii. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, *et seq.*;

jj. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*;

kk. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01, *et seq.*;

ll. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, *et seq.*

mm. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Okla. Stat. tit. 15 § 751, *et seq.*;

nn. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq.*;

oo. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, *et seq.*;

pp. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws § 6-13.1-1, *et seq.*;

qq. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq.*;

rr. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1, *et seq.*;

ss. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq.*;

tt. Defendants have engaged in unfair competition or unfair or deceptive

acts or practices in violation of Tex. Bus. & Com. Code § 17.41, *et seq.*;

uu. Defendant have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code Ann. § 13-11-1, *et seq.*;

vv. Defendant have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. Tit. 9, § 2451, *et seq.*;

ww. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, *et seq.*;

xx. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wash. Rev. Code § 19.86.010, *et seq.*; Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of W. Va. Code § 46A-6-101, *et seq.*;

yy. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. § 100.20, *et seq.*;

zz. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. § 40-12-100, *et seq.*; and

aaa. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 23 L.P.R.A. § 1001, *et seq.*, the applicable statute for the Commonwealth of Puerto Rico.

147. Each Defendant's conduct constitutes trade or commerce or other actionable activity within the meaning of the above statutes.

148. Each Plaintiff and other Class Member is a consumer or person aggrieved by Defendant's misconduct within the meaning of the above statutes.

149. Each Defendant's conduct as alleged herein constitutes unfair, deceptive, misleading, or otherwise actionable practices as to each Defendant's conduct concerning the purported effectiveness of its PE Drugs for treating the indications identified.

150. To the extent applicable, each Defendant knew, intended, or should have known that their fraudulent and deceptive acts, omissions, or concealment would induce reliance and that reliance can be presumed under the circumstances. As a direct and proximate result of each Defendant's unfair methods of competition and unfair or deceptive acts or practices, Plaintiff and other Class Members have suffered damages– an ascertainable loss – in an amount to be proved at trial.

151. To the extent applicable, pre-suit notice and/or a demand letter was sent to each Defendant prior to the filing of the Complaint.

SEVENTH COUNT
UNJUST ENRICHMENT

152. Plaintiff re-alleges and incorporates the preceding paragraphs as if full set forth herein.

153. As alleged herein, each Defendant was unjustly enriched at the expense of Plaintiffs and other Class Members by virtue of the latter's paying for Defendant's PE Drugs.

154. Each Defendant profited immensely from the sale of their products in the United States for human consumption. On top of that, because each Defendant's PE Drugs were misbranded, their distribution and sale in the United States was illegal.

155. Plaintiff and other Class Members were unjustly deprived of money obtained by each Defendant as a result of the improper amounts paid for Defendant's PE Drugs. It would be inequitable and unconscionable for each Defendant to retain the profit, benefit,

and other compensation obtained from Plaintiff and other Class Members as a result of their wrongful conduct alleged in this Complaint. There is no adequate remedy at law for Plaintiff and other Class Members.

156. Plaintiff and other Class Members are entitled to seek and do seek restitution from each Defendant as well as an order from this Court requiring disgorgement of all profits, benefits, and other compensation obtained by each Defendant by virtue of its wrongful conduct.

EIGHTH COUNT

NEGLIGENCE

157. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth herein.

158. Each Defendant owed a duty to Plaintiff and the Class to use and exercise reasonable and due care in the manufacturing and sale of its PE Drugs.

159. Each Defendant owed a duty to Plaintiff and the Class to ensure that the PE Drugs it sold in the United States were effective for the indications identified and not misbranded.

160. Each Defendant owed a duty of care to Plaintiff and the Class because they were the foreseeable, reasonable, and probable user of PE Drugs and victim of Defendant's fraudulent and deceptive activities. Each Defendant knew, or should have known, that its PE Drugs were not effective for treating the indications identified and were misbranded, and each was in the best position to uncover and remedy these shortcomings.

161. Each Defendant failed to do this. Defendant inadequately oversaw the

research, development, testing and sale of its own PE Drugs. Each Defendant knew that ignoring the research, development and testing issues surrounding its PE Drugs would damage Plaintiffs and the Class and increase its own profits.

162. Each Defendant maintained or should have maintained a special relationship with Plaintiffs and the Class, as they were obligated to ensure that its PE Drugs were effective to treat the indications identified and not misbranded.

163. Each Defendant's own actions and inactions created a foreseeable risk of harm to Plaintiff and the Class. Each Defendant's misconduct included, but was not limited to, failing to oversee actions taken in the manufacture and sale of its PE Drugs.

164. Each Defendant breached duties owed to Plaintiff and the Class by failing to exercise reasonable care sufficient to protect the interests and meet the needs of Plaintiff and the Class.

165. As a direct and proximate result of each Defendant's negligent conduct, Plaintiff and the Class has suffered injury and are entitled to damages in an amount to be proven at trial.

NINTH COUNT
NEGLIGENCE PER SE

166. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth herein.

167. Each Defendant owed a duty to Plaintiff and the Class to use and exercise reasonable and due care in the manufacturing and sale of its PE Drugs.

168. Each Defendant owed a duty to Plaintiff and the Class to ensure that the PE

Drugs it sold in the United States were effective at treating the indications identified and were not misbranded.

169. Each Defendant owed a duty to Plaintiff and the Class because each state, territory, and possession has adopted/or adheres to federal standards, including but not limited to the following parallel state statutes:

- Alabama Code §§ 20-1-24 and -27(1);
- Alaska Statutes § 17.20.290(a)(1);
- Arizona Statutes §§ 32-1965(1), (2) and -1966(3);
- Arkansas Code § 20-56-215(1);
- California Health and Safety Code §§ 111295 and 111400;
- Colorado Statutes §§ 25-5-403(1)(a),(b) and -414(1)(c);
- Title 16, Delaware Code §§ 3302 and 3303(2);
- District of Columbia Code § 48-702(2);
- Florida Statutes §§ 499.005(1) and .006(3);
- Georgia Code § 26-3-3(1);
- Hawaii Revised Statutes §§ 328-6(1) and -14(1)(B)(ii);
- Idaho Code § 37-115(a);
- Chapter 410, Illinois Statutes §§ 620/3.1 and /14(a)(2)(B);
- Iowa Code §§ 126.3(1) and .9(1)(c);
- Kentucky Statutes § 217.175(1);
- La. Rev. Stat. § 40:601, *et seq.*;
- Maryland Code, Health–General §§ 21-216(c)(5)(2) and -256(1);
- Massachusetts General Laws chapter 94 §§ 186 and 190;
- Minnesota Statutes §§ 151.34(1) and .35(1);
- Missouri Statutes § 196.015(1);
- Montana Code §§ § 50-31-305(3) and -501(1);

- Nebraska Revised Statutes §§ 71-2461(2) and -2481;
- Nevada Statutes § 585.520(1);
- New Hampshire Revised Statutes §§ 146:1(I) and :4(V);
- New Mexico Statutes §§ 26-1-3(A) and -10(A);
- New York Education Law § 6811;
- North Dakota Century Code §§ 19-02.1-02(1) and .1-13(3);
- Ohio Code § 3715.52(A)(1);
- Oklahoma Statutes title 63 § 1-1402(a);
- Title 35, Pennsylvania Statutes § 780-113(a)(1);
- Title 21, Rhode Island General Laws § 21-3-3(1);
- South Carolina Code §§ 39-23-30(a)(2)(B) and -80(A)(1);
- South Dakota Code §§ 39-15-3 and -10;
- Title 18, Vermont Statutes § 4052(1);
- Virginia Code § 54.1-3457(1);
- West Virginia Code §§ 16-7-1 and -2(a)(3); and
- Wyoming Statutes §§ 35-7-111(a)(i)–(iv), (vi) and -116.

170. Each Defendant failed to comply with federal standards, including branding standards.

171. As a result of each Defendant's failures to do so, each Defendant's own actions and inactions created a foreseeable risk of harm to Plaintiff and the Class.

172. As a direct and proximate result of each Defendant's negligent conduct, Plaintiff and the Class have suffered injury and are entitled to damages in an amount to be proven at trial.

PRAYER FOR RELIEF

For these reasons, Plaintiff prays for the following judgment:

A. An order certifying this action as a class action;

B. An order appointing Plaintiff as Class Representative, and appointing undersigned counsel as Class Counsel to represent the Class;

C. A declaration that each Defendant is liable under each and every one of the above-enumerated causes of action;

D. An order awarding appropriate preliminary and/or final injunctive relief against the conduct of each Defendant described above;

E. Payment to Plaintiff and Class Members of all damages, exemplary or punitive damages, and/or restitution associated with the conduct for all causes of action in an amount to be proven at trial, including but not limited to the full amounts paid for the PE Drugs; the costs to replace or return PE Drugs; and/or the increases in the amounts paid for non-misbranded substitute products;

F. An award of attorneys' fees, expert witness fees, and costs, as provided by applicable law and/or as would be reasonable from any recovery of monies recovered for or benefits bestowed on the Class Members;

G. An award of statutory penalties to the extent available;

H. Interest as provided by law, including but not limited to pre-judgment and post-judgment interest as provided by rule or statute; and

I. Such other and further relief as this Court may deem just, equitable, or proper.

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury of all issues in this action so triable.

Dated: September 20, 2023

/s/ Ruben Honik

Ruben Honik
David J. Stanoch, Of Counsel
HONIK LLC
1515 Market Street, Suite 1100
Philadelphia, PA 19102
Tel : (267) 435-1300
E-mail: ruben@honiklaw.com
david@honiklaw.com